

264-704

08-06-2009

Tachet 1/4

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Gregory C. Mattern  
Regulatory Product Manager  
Bayer CropScience LP  
2 T.W. Alexander Drive  
Research Triangle Park, NC 27709

AUG 06 2009

Subject: Pyrimethanil Technical  
EPA Registration No. 264-704  
Your Amendment dated May 01, 2008, New use stone fruit and citrus  
PRIA Decision No. 393251

Dear Mr. Mattern:

The labeling referred to above, submitted in connection with registration under section under 3(c)(7)(b) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) is acceptable provide the following changes are made:

1. Within the ingredients statement, add a line for the total percent amount for the active ingredient and other ingredients which reads as follows "Total ..... 100%."
2. On page 2, second sentence under the section "Only For Formulation Into a Fungicide, for the Following Uses" section, revise the word, "product" to "products".
3. On page 2, within the "Storage and Disposal" section, add the word, "secure" prior to the word, "dry" so that the sentence reads, "Store in a cool, secure, dry area."
4. On page 2, add the phrase, "Manufactured for" above the company name and address.

New Conditional Data Requirements:

1. Submit an Immunotoxicity study (OPPTS Guideline No. 870.7800) by April 2010.
2. Submit a Tier II Seedling Emergence and Vegetative Vigor tests (OPPTS Guideline No. 850.4225 and 850.4250) (123-1a and b) by September 2010.
3. The standard for pyrimethanil at the National Pesticide Standards Repository has expired. You must either recertify the lot in the repository, and send in an updated certificate of analysis (COA), or submit a new standard (with a different lot number) if the previous lot can not be recertified. If a new COA is submitted, you may fax the documentation to the repository at (410)305-2999 or you may mail it to the address below.

2  
4

If you are submitting a new standard, it should be sent to the Analytical Chemistry Branch (ACB), which is located at Fort Meade, to the attention of Theresa Cole at the following address:

USEPA  
National Pesticide Standards Repository/Analytical Chemistry Branch  
701 Mapes Road  
Fort George G. Meade, MD 20755-5350  
(Please note that the mail will be returned if the extended zip code is not used.)

Remaining Conditional Data Requirements identified in the 8/13/2004 Registration Notice:

1. Submit a Mouse Carcinogenicity study (OPPTS Guideline No. 860.4200) by March 2010.
2. The Agency acknowledges receipt of the Freshwater Fish Life Cycle study (OPPTS Guideline No.850.1500), MRID No. 475169-01 and notes the review is pending.
3. The Agency notes the Estaurine/Marine Fish Early Life Stage study (OPPTS Guideline 850.1400) is reserved. This data may be required at a later date pending review of the Freshwater Fish Life Cycle study.
4. The Agency acknowledges receipt of production information for 2005-2008.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). One copy of the label stamped "Accepted with Comments" is enclosed for your records. If you have any questions, please contact Tamue L. Gibson by phone at (703) 305-9096 or via email at [gibson.tamue@epa.gov](mailto:gibson.tamue@epa.gov).

Sincerely,

Mary L. Waller  
Product Manager (21)  
Fungicide Branch  
Registration Division (7505P)

Enclosure

3  
4

# PYRIMETHANIL Technical

For Formulation Of Fungicides Only.

Formulators who use this product are responsible for obtaining EPA registration for their formulated products.

**ACTIVE INGREDIENT:**

Pyrimethanil: 4,6-dimethyl-N-phenyl-2-pyrimidinamine ..... 98.0%

OTHER INGREDIENTS:..... 2.0%

EPA Reg. No. 264-704

EPA Est. No.

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

For MEDICAL And TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577

For PRODUCT USE Information Call 1-888-BAYER (1-888-283-6847).

### FIRST AID

IF SWALLOWED:	<ul style="list-style-type: none"> <li>• Immediately call a poison control center or doctor for treatment advice.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
IF IN EYES:	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<p style="text-align: center;">For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577.</p>	
<p style="text-align: center;">Have the product container or label with you when calling a poison control center or doctor or going for treatment.</p>	
<p><b>NOTE TO PHYSICIAN:</b> Possible mucosal damage may contraindicate the use of gastric lavage. May pose an aspiration pneumonia hazard.</p>	

### PRECAUTIONARY STATEMENTS

#### HAZARD TO HUMANS AND DOMESTIC ANIMALS CAUTION

Harmful if swallowed. Avoid contact with skin and clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove contaminated clothing and wash before reuse.

#### ENVIRONMENTAL HAZARDS

This pesticide is toxic to invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its label.

For use only by manufacturers in the formulation of fungicides. Subsequent formulators are responsible for providing documentation to support registration of their product. This product requires further mixing before use.

**ACCEPTED**  
**with COMMENTS**  
**In EPA Letter Dated:**  
**AUG 06 2009**

**Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
as amended, for the pesticide  
registered under EPA Reg. No.  
264-704.**

5/15

Only For Formulation Into a Fungicide, for the Following Uses: tree nuts, bulb vegetables, grapes, citrus fruit, stone fruit, pome fruits, tuberous and corn vegetables, strawberries and tomatoes. This product may be used to formulate product for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with the U.S. EPA submission requirements regarding support of such use(s).

This product is not registered for use at residential sites.

**STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage or disposal.

**PESTICIDE STORAGE:** Store in original container and keep tightly closed. Store in a cool dry area.

**PESTICIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available. Completely empty bag into application equipment. Then dispose of bags in a sanitary landfill or by incineration, or if allowed by State and Local Authorities, by burning. If burned, stay out of smoke.

**DISCLAIMER AND INDEMNITY FOR FORMULATORS' USES**

THE MANUFACTURER EXPRESSLY DISCLAIMS ALL LIABILITY FOR CLAIMS AND ACTIONS (WHETHER BASED ON CONTRACT, TORT, STRICT LIABILITY OR BREACH OF WARRANTY) ARISING OUT OF, RESULTING FROM OR CONNECTED WITH A FORMULATION CONTAINING THIS PRODUCT WHEN USED FOR ANY PURPOSE OTHER THAN THOSE USES SET FORTH IN (1) ABOVE. THE MANUFACTURER HAS NOT DEVELOPED SCIENTIFIC DATA TO SUPPORT, NOR HAS IT EXPLICITLY OR IMPLICITLY APPROVED, ANY USES OTHER THAN THOSE IN (1) ABOVE.

ANY FORMULATOR OR BUYER WHO USES THIS PRODUCT IN FORMULATIONS FOR ANY USE OTHER THAN THOSE STATED IN (1) ABOVE ASSUMES ALL LIABILITY FOR CLAIMS AND ACTIONS ARISING OUT OF , CONNECTED WITH OR RESULTING FROM SUCH USE AND AGREES BY SO USING THIS PRODUCT TO INDEMNIFY AND HOLD HARMLESS THE MANUFACTURER FROM SUCH CLAIMS AND ACTIONS.

THIS DISCLAIMER AND INDEMNITY IS IN ADDITION TO, NOT IN LIEU OF, THE BELOW DISCLAIMER AND LIMITATIONS.

**IMPORTANT: READ BEFORE USE**

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

**CONDITIONS:** The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience. All such risks shall be assumed by the user or buyer.

**DISCLAIMER OF WARRANTIES:** TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

**LIMITATIONS OF LIABILITY:** TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE'S ELECTION, THE REPLACEMENT OF PRODUCT.

**MANUFACTURED FOR**



**Bayer CropScience**

Bayer CropScience LP  
P.O. Box 12014, 2 T.W. Alexander Drive  
Research Triangle Park, North Carolina 27709  
1-866-99BAYER (1-866-992-2937)

Pyrimethanil Technical (PENDING) 04/17/08, Resubmitted 07/30/09